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38834 7590 10/12/2007 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW			EXAMINER	
			MATTER, KRISTEN CLARETTE	
SUITE 700 WASHINGTON, DC 20036			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Ţ	Application No.	Applicant(s)				
Office Action Comment	10/506,971	DELACHE ET AL.				
Office Action Summary	Examiner	Art Unit				
	Kristen C. Matter	3771				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period was reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	I.  lely filed  the mailing date of this communication.  D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 08 Se	) Responsive to communication(s) filed on <u>08 September 2004</u> .					
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>24-50</u> is/are pending in the application	١.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>24-50</u> is/are rejected.	6)⊠ Claim(s) <u>24-50</u> is/are rejected.					
	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10) $\boxtimes$ The drawing(s) filed on $9/8/04$ is/are: a) $\square$ accepted or b) $\boxtimes$ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
the state of the s						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application						
Paper No(s)/Mail Date <u>9/8/04</u> . 6) Other:						

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#### **DETAILED ACTION**

### **Drawings**

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "11" has been used to designate both outlet and cover.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 2,  $d_1$ , and  $d_2$ .

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 95 (Figure 8), 51 (Figure 10), R<sub>2</sub>, R<sub>3</sub> (Figure 11), 102, 104, 108, 110, 112, 114, 116, 130, 140 (Figure 14), A<sub>M</sub>, E<sub>1</sub>, P<sub>1</sub>, and P<sub>2</sub> (Figure 16b).

The drawings are objected to because in Figures 1, 10, 12, and 14, what each box represents should be fully written out (as opposed to just a reference number) to make the Figure more easily understood since the boxes do not resemble the elements they are representing.

In Figure 2, a bracket should be drawn indicating that all of the separate elements are connected and belong in one figure as opposed to being multiple figures on the same page.

Figures 4a and 4b are hard to read and examiner is unsure what these figures are representing (i.e., what is SB, SA, SC, EA, EB, EC, for example). In addition, what are the lines at the top left hand corner of Figure 4b representing?

In Figure 7, the equation should be moved to the written description.

In Figure 12, there are empty, unlabeled components on the left hand side of the figure.

Examiner is unsure what these represent.

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### Specification

The spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

The specification is replete with grammatical and idiomatic errors involving spacing and noun/verb agreement. For example:

On page 6, line 9, there are two spaces between "Figure" and "4b" and on line 34, "16 b" should be --16b--.

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On page 7, line 3, "mean" should be --means--, on line 10 "as" should be --has--, on line 16, "mean" should be --means--, on line 17, "detect" should be --detected--, and on line 33, "composed" should be --compose--.

On page 10, line 26, "The figures 8 represents" should apparently be changed to --Figure 8 represents--.

The previous are just examples of the types of grammatical errors found throughout the specification, but these exists throughout the entire disclosure.

In addition to grammatical errors, for example:

On page 7, line 27, examiner is unsure what is meant by "IrDa."

On page 8, line 24, examiner is unsure what is being enabled to measure the tension.

On page 12, "Tableau 1" should be changed to English.

On page 16, line 18, the language "a strip wound technique allowing to go to 0.05 mm thickness" is confusing because examiner is not sure what is allowed to go to the desired thickness (i.e., there appears to be words missing).

On page 17, line 10, "allows to modulate" is confusing because examiner is not sure what is allowed to modulate (i.e., there appears to be words missing).

On page 24, line 16 "On the figures?" should be corrected to include what figure is being referred to.

Applicant is strongly encouraged to carefully proofread the entire disclosure and correct mistakes similar to those mentioned above.

## Claim Objections

Claims 24, 31, 34-37 and 39-43 are objected to because of the following informalities:

In claim 24, line 2, "this patient" should be changed to --the patient-- because as currently written it is somewhat confusing.

In claim 31, line 3, "the three stator sectors" should be changed to --the at least three stator sectors-- because there can be more than three sector

In claim 34, line 4, "the pressure delivered" should be changed to --a pressure delivered-because this pressure has not been previously introduced in the claims.

In claim 35, line 8, claim 36, line 2, and claim 37, line 6, "P<sub>M</sub>" should be deleted or parentheses added around it.

In claim 39, line 2, and claim 40, line 4, " $(E_1, E_2 \text{ or } E_3)$ " should be deleted because it is somewhat unclear as to what these are defining.

In claim 41, line 3, "set" should be changed to --sets-- for proper verb noun agreement and "PM" should be deleted or parentheses added around it. Also, on the last line, "to patient's breathing" should be changed to --to the patient's breathing-- to correct the typographical mistake.

In claim 42, on line 2, "comprise" should be changed to --comprises-- to correct the typographical mistake.

In claim 43, line 7, "KT" should be deleted or parentheses added around it.

Appropriate correction is required.

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# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "the impeller" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "the power supply" in line 3. There is insufficient antecedent basis for this limitation in the claim. Also, on line 9, use of the language "thus enabling to" is confusing because it is unclear what is being enabled to measure the back EMF.

Claim 28 recites, "coils connected with only one wire" in line 3. This is somewhat confusing because it is unclear whether the sectors are connected to each other by only one wire or to another component, such as the power supply.

Claim 37 recites the limitation "the clinician" in line 2. There is insufficient antecedent basis for this limitation in the claim. Also, on line 5, use of the language "said estimation module providing the pressure PM" makes it unclear what pressure is being referred to (i.e., the treatment pressure or the pressure to apply).

Claim 38, in line 3, use of the language "said estimation module providing the pressure PM" makes it unclear what pressure is being referred to (i.e., the treatment pressure or the pressure to apply).

Claim 42 recites the limitation "said first tube extremity" in line 3, "the extremity of the tube connected to the blower outlet" on line 5, "said airflow computation module" on line 6, and "the tube airflow resistance coefficient" in line 7. There is insufficient antecedent basis for these limitations in the claim.

Claim 43 recites the limitation "the instruction to stop" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 44 recites the limitation "the data" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests deleting the word "the".

Claim 45 recites the limitation "the binary data" in line 3, "the apparatus sensors" in line 3, and the frequency in line 4. There is insufficient antecedent basis for these limitations in the claim. Furthermore, this claim appears to be directed to the elements defining the communication module, but lines 6-11 do not make a complete, coherent sentence because the claimed elements and what appears to be functional language do not seem to fit together. Examiner is unsure what element is connected to the external power supply, for example, and are the FSK modulator and FSK demodulator the only claimed elements of the communication module in this claim?

Claims 26-30, 32, 33, and 46-50 are dependent on claim 24 and are therefore rejected for the reasons outlined above with respect to claim 24.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 24-29, 32-33, and 44-50, as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoeb (US 2002/0000228) in view of Makaran (US 5,744,921).

Regarding claims 24, 48, and 49, Schoeb discloses a apparatus to assist in a patient's respiration by delivery of air during CPAP treatment comprising an impeller rotated by an electric motor comprising a rotor (3c) and a stator (2d) having at least three sectors allowing rotation of the rotor by a change in each sector's polarity constituting one step of the rotor's rotation (paragraph 0026), and a driving unit controlling changes in each sector's polarity (paragraph 0026) such that the blower can achieve fast accelerations and decelerations within one patient's breath step (paragraph 0028). Schoeb is silent as to the driving unit comprising means to sense a back electromotor force (BEMF). However, Makaran discloses, in an electromotor configured for fast accelerations and decelerations, a sensing circuit to sense the BEMF for predicting the position of the rotor in a blower system (column 5, lines 45-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a means for sensing the BEMF as taught by Makaran in the system disclosed by Schoeb in order to determine the position of the rotor. Furthermore, Makaran teaches the BEMF can fluctuate from positive to negative values, so absent a critical teaching and/or showing of unexpected results from using a "zero value" of the BEMF to change the sectors polarity, this is considered an obvious design consideration to one of ordinary skill in the art because it appears that the value at which the sectors polarity is changed is a result of routine experimentation to optimize energy consumption of the system. Although not explicitly stated in Schoeb, it is well

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known that CPAP systems deliver air through masks to patients and are often used for treating sleep apnea (see US 6,152,129 for extrinsic evidence).

Regarding claim 25, Schoeb discloses at least three sectors (paragraph 0026), each sector is connected to a controller (and inherently a power supply). Although Schoeb does not explicitly disclose a positive plot and a negative plot, it is well known in the field that electromotors work by alternating positive and negative current through the sectors of a stator to achieve steps for rotating the rotor. For example, see Makaran who teaches positive and negative currents to drive the rotor from an AC power source (column 4, lines 10-15) to energize various sectors of the stator in sequence to drive the rotor (column 3, lines 29-34). Therefore, it appears that Schoeb's device would inherently involve alternating positive, negative, and no current conditions to each of the stators in order to drive the rotor. At a minimum, it would have been an obvious design consideration to one of ordinary skill in the art at the time of the invention to do so, because it would have provided an effective and efficient means for driving the rotor. In addition, it appears as though the modified Schoeb device would perform equally well with the positive and negative plots connected to the sectors for driving the rotor. In addition, Makaran discloses the positive and negative plots as well as ground references for sensing the BEMF.

Regarding claim 26, although Schoeb is silent as to pulse width modulation, Makaran discloses pulse width modulation as a well known means of applying the tension (column 6, lines 38-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used pulse width modulation as taught by Makaran in the system disclosed by Schoeb for minimizing or reducing power dissipation in the coils.

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Regarding claim 27, Schoeb is silent as to the specific number of sectors, but Schoeb does disclose more than one sector and no limit to a maximum number. Therefore, absent a critical teaching and/or showing of unexpected results from using a three sector stator, examiner contends it is a matter of obvious design choice to one of ordinary skill in the art to use a three sector stator for producing the rapid accelerations/decelerations using a minimal or reduced number of stators. In addition, it appears as though the modified Schoeb device would perform equally well with a three sector stator. Although Schoeb doesn't disclose the specifics of the magnet, dipole magnets are well known for use as rotors in electromotors, as taught by Makaran (column 6, lines 65-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to been obvious to use a dipole magnet for efficiently producing the rotation of the rotor because this is a well known and commonly used technique in electromotors.

Regarding claim 28, Schoeb discloses the windings (2b) but is silent as to the number of wires connecting the windings. However, absent a critical teaching and/or a showing of unexpected results from connecting the sectors by only one wire, examiner contends connecting the sectors by only one wire is a matter of obvious design consideration to one of ordinary skill in the art because it would have provided the simplest method (and least materials) for electrically connecting the sectors for running the current through. In addition, see Figure 1 of Makaran in which it appears that the windings are connected to the controller by only one wire.

Regarding claim 29, the device disclosed by Schoeb would inherently change the sectors polarity after a given time (paragraph 0028) to drive the rotor. In addition, Makaran discloses that the controller adjusts the excitation to the windings based on the measured BEMF values (column 5, line 60-column 6, line 35).

Regarding claim 32, Makaran discloses a power supply manager that can be connected to a positive power supply, a current sensor, a comparator, a load resistor, and a means to switch the load resistor between positive and ground (see Figure 1 and column 5, line 45-column 6, line 35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Schoeb's device with the power supply manager taught by Makaran in order to conserve power.

Regarding claim 33, absent a critical teaching and/or a showing of unexpected results, examiner contends the size of the tube between the blower and a patient mask is an obvious design consideration to one of ordinary skill in the art because tubes of less than 22 mm are well known in CPAP systems (for extrinsic evidence see US 2007/0119454). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a tube with a diameter less than 22 mm in the modified Schoeb device for making the system less bulky and more comfortable for the patient.

Regarding claim 44, the power supply manager disclosed by Makaran above with respect to claim 32 would inherently have some sort of communication module for transmitting data, else no power would be delivered and the manager would not be able to "compare" the BEMF signals with reference values for example.

Regarding claim 45, although not explicitly disclosed, Schoeb would inherently have a FSK modulator because the device has sensors connected to the controller (paragraph 0038) and the controller, sectors, and sensors must all communicate with other, thereby binary data readable by the computer must be transformed to a corresponding voltage frequency transmitted by the power supply to allow the rotor speed to be adjusted.

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Regarding claims 46 and 47, Schoeb discloses a housing (3a), which would provide at least some phonic insulation, and high speeds of rotation for the impeller. In addition, size gives no definite limitation to the claim because "a size" could be interpreted to mean any dimension of the impeller. Examiner is assuming the applicant is referring to a diameter of less than 60 mm, which is a matter of obvious design consideration because small sized impellers are well known in the field by persons of ordinary skill in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make Schoeb's modified impeller less than 60 mm in order to reduce weight of the system, make the system portable, and to minimize stress on the system from the repeated abrupt starting and stopping. For extrinsic evidence see US 5,875,783, which teaches an impeller with a diameter of 50 mm in a respirator device. In addition, the modified Schoeb reference does not disclose between 15 and 45 blades. However, absent a critical teaching and/or showing of unexpected results from using the claimed number of blades, the number of blades is considered an obvious design consideration to one of ordinary skill in the art at the time of the invention as a mere duplication of parts for forcing air into the patient's mask and into the lungs. Furthermore, it appears as though the modified Schoeb device would perform equally well with 27 or 15-45 blades.

Regarding claim 50, Schoeb discloses a sheet metal stator. How the stator is obtained is considered a product by process limitation. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777

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F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). In addition, see also *In* re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Claims 34-41, as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoeb and Makaran as applied to claim 24 above, and further in view of DeVries et al. (US 5,694,926).

Regarding claim 34, although Schoeb discloses pressure sensors for example, to the extent, if any, that the reference does not disclose adjusting the pressure by an estimation module depending on the determination that inspiration or exhalation is occurring, DeVries et al. discloses, in a ventilator, an impeller that is capable of rapid accelerations and decelerations within a patient's breath step that applies the accelerations and decelerations as a function of the breath cycle (i.e., whether the patient is inhaling or exhaling) (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have controlled the pressure as a function of the breathing cycle as taught by DeVries et al. in the modified Schoeb device because it would have allowed for a Bi-PAP treatment of a patient, for example, depending on the desired therapy for the patient.

Regarding claims 35 and 36, Schoeb discloses pressure measurement near the mask (paragraph 0038) and DeVries et al. discloses that pressure can be measured at the mask and delivered as a function of time.

Regarding claims 37 and 38, DeVries et al. discloses a non-volatile memory (column 19, lies 15-20) and that clinicians and patient's can enter settings (including treatment pressures) for

controlling the pressure delivered to the patient (column 10, line 5-column 13, line 20; column 16, line 45-column 17, line 10) within set boundaries.

Regarding claims 39-41, DeVries et al. discloses detecting events are occurring (including inspiration and expiration by pressure measurements) and to adjust the delivered pressure based on the events (i.e., delivers one pressure during inspiration and a second pressure during expiration).

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoeb and Makaran as applied to claim 24 above, and further in view of Elrod, Jr. (US 5,508,575).

Regarding claim 30, Schoeb discloses conventional electric motors with bearings (paragraph 0033) but is silent as to the location of the rotor being shifted outside the stator. However, Elrod, Jr. discloses, in an electromotor, a rotor that is shifted outside the stator to cause a preload on the bearings (column 1, lines 45-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have offset the rotor and stator as taught by Elrod, Jr. in the modified Schoeb device in order to preload the bearings by a constant magnetic force.

Regarding claim 31, Elrod, Jr. is silent as to the rotor being shifted outside of the stator at an equal distance of each of the stators. However, absent a critical teaching and/or a showing of unexpected results from shifting the rotor in this manner, examiner contends it is an obvious design consideration to one of ordinary skill in the art because the amount of shift is a result effective to establishing the magnetic bias, such that it would be obvious to shift the rotor outside

of the stator at an equal distance of each of the three stator sectors in order to optimize the amount of bias magnetic force on the bearings.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoeb,

Makaran, and DeVries et al. as applied to claim 34 above, and further in view of Berthon-Jones

(US 6,152,129). Schoeb is silent as to a pressure sensor at a first tube extremity and another for

measuring the pressure at the output to the blower such that the airflow can be calculated from

these pressures and a known tube coefficient. Berthon-Jones discloses, in a ventilator, first and
second pressure sensors for measuring pressure at a first tube extremity and an output to a blower
such that airflow can be calculated form a known tube coefficient (see Figure 2a and abstract).

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoeb,

Makaran, and DeVries et al. as applied to claim 34 above, and further in view of Hill et al. (US 6,401,713). Schoeb is silent as to a starting means that stops the blower after a duration if no activity is sensed. However, Hill et al. disclose, in a ventilator, that automatic on/off features that turn the system off upon the patient removing the mask are well known in the field (column 11, lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the modified Schoeb device with an automatic on/off feature as taught by Hill et al. in order to conserve power when the device is not needed for treatment.

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### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kullik is cited to show small sized impellers in ventilators, Berthon-Jones (US 2007/0119454) is cited to show small-diameter tubes n ventilators, and Daly et al. is cited to show another high-speed impeller in a ventilator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen C. Matter Examiner

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10/3/07